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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/921,994	08/03/2001	Michael R. Bowman	GIN-5381	7090

7590

11/06/2002

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NEW YORK, NY 10112-3801

EXAMINER

FREDMAN, JEFFREY NORMAN

ART UNIT

PAPER NUMBER

1637

DATE MAILED: 11/06/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/921,994

Applicant(s)

BOWMAN, MICHAEL R.

Examiner

Jeffrey Fredman

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-23 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: ____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-6, 18, drawn to nucleic acids and host cells, classified in class 536, subclass 23.1.
 - II. Claim 7, drawn to nonhuman mammals, classified in class 800, subclass 2.
 - III. Claims 8-10, 12, drawn to polypeptides and methods of making polypeptides, classified in class 530, subclass 350.
 - IV. Claim 11, drawn to antibodies, classified in class 435, subclass 387.1.
 - V. Claims 13-14, drawn to methods of polypeptide detection, classified in class 435, subclass 7.1.
 - VI. Claim 15, drawn to compounds which bind polypeptides, classified in class 514, subclass 1.
 - VII. Claims 16-17, drawn to methods for detection of nucleic acids, classified in class 435, subclass 6.
 - VIII. Claims 19-23, drawn to screening for compounds which interact with polypeptides, classified in class 436, subclass 501.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions in Group I and in Groups II, III, IV, V, VI and VIII are distinct.

Inventions are distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different

Art Unit: 1637

effects. In the instant case the different inventions are distinct because nucleic acids are chemically and structurally different from nonhuman mammals, from polypeptides, from antibodies and from methods of using or screening polypeptides. In particular, nucleic acids differ in their mode of operation, operating by hybridization or by encoding information which must be transcribed and translated while proteins operate by interaction and/or enzymatic activity. Further, proteins and nucleic acids have different functions and effects in cells with nucleic acids serving as the genetic information.

3. Inventions in Group I and in Group VII are related as product and process of use.

The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the nucleic acid product can be used in the protein expression method, in the nucleic acid detection method of Group VIII, in nucleic acid purification methods, in amplification methods or in microarray methods.

4. Inventions in Group II and in Groups III-VIII are distinct. Inventions are distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects. In the instant case the different inventions are distinct because the nonhuman mammals are physically, structurally and biologically different from the proteins, the antibodies, and the methods of making, screening and using proteins and nucleic acids. The nonhuman mammals differ in operation, in function and effect from each of the other groups with the

Art Unit: 1637

mammals being living organisms while the rest of the claims are drawn to isolated products or methods.

5. Inventions in Group III and in Groups IV, VI and VII are distinct from one another.

Inventions are distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects. In the instant case the different inventions are distinct because the polypeptide of Group III differs structurally and chemically from the antibody of Group IV, the compounds of Group VI and is not functional in the nucleic acid detection method of Group VII. The polypeptide differs in operation and effect from the antibodies and compounds.

6. Inventions in Group III and in Groups V and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polypeptides can be used in the detection method of Group V, in the screening method of Group VIII, in enzymatic or functional assays or in production of antibodies.

7. Inventions in Group IV and in Group V are related as product and process of use.

The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially

Art Unit: 1637

different process of using that product (MPEP § 806.05(h)). In the instant case, the antibodies can be used in the detection method of Group V, in purification methods, in generation of aptamers or in gel shift assays.

8. Inventions in Group IV and in Group VIII are distinct from one another.

Inventions are distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects. In the instant case the different inventions are distinct because the antibody of Group IV differs structurally and chemically from the compounds found in Group VIII and because the product is not used in the method of Group VIII and differs in operation and effect from the Group VIII method.

9. Inventions in Group V and in Groups VI, VII and VIII are distinct. Inventions are distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects. In the instant case the different inventions are distinct because the method of polypeptide detection of Group V differs in mode of operation, function and effect from the compounds of Group VI, from the nucleic acid method of Group VII and from the compound screening method of Group VIII.

10. Inventions in Group VII and in Groups VI and VIII are distinct from one another. Inventions are distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects. In the instant case the different inventions are distinct because the method of

Art Unit: 1637

nucleic acid detection of Group VII differs in mode of operation, function and effect from the compounds of Group VI and from the compound screening method of Group VIII.

11. Inventions in Group VIII and in Group VI are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product can be made by the screening method of Group VIII or by chemical synthesis.

12. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

13. A telephone call was made to Debra Milasinic on November 6, 2002 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is 703-308-6568. The examiner can normally be reached on 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone numbers

Art Unit: 1637

for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Jeffrey Fredman
Primary Examiner
Art Unit 1637

November 6, 2002